White Paper

Understanding ISO 13485: A Brief, Yet Comprehensive, Overview

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OVERVIEW

If you work in the medical device industry, you are aware of the importance of ISO 13485, also referred to as ISO 13485–Quality Management Systems—Requirements for Regulatory Purposes and ISO 13485:2003. This white paper provides a brief, yet comprehensive, overview of the standard, and examines how obtaining ISO 13485 certification can open doors to untapped domestic and international business opportunities. It also explains how to avoid becoming one of the 50 percent of device companies that fail to obtain recertification due to inadequate manual processes.

(Editor's note: This standard is being revised. ISO 13485:201X, as the revision is being referred to, is expected to be available in Q1 of 2016.)

What is ISO 13485?

ISO 13485 is a series of requirements that help medical device manufacturers develop a quality management system. According to the official ISO 13485 standard, these requirements "can be used by an organization for the design and development, production, installation and servicing of medical devices, and the design, development, and provision of related services."[1]

Although ISO 13485 is a stand-alone document, it is often harmonized with ISO 9001, the world's leading quality management standard, which, as of this writing, is also under revision. According to ISO's website, the revised 9001 standard is expected to be published by the end of 2015. (Watch this video to learn more about the proposed changes to ISO 9001.)

How Does ISO 13485 Differ from ISO 9001?

The most fundamental difference between the two standards is that ISO 13845 is tailored specifically to medical device companies, whereas ISO 9001 can be used by any company, of any size, within any industry sector. Additionally, ISO 9001 requires the certified company or organization to demonstrate continual improvement. By contrast, ISO 13485 requires only that the organization demonstrate that its quality system is effectively implemented and maintained.

Another principal difference is that ISO 13485 excludes the ISO 9001 requirements regarding customer satisfaction, focusing instead on regulatory requirements as a management responsibility. Finally, unlike ISO 9001, 13485 places great emphasis on the importance of risk. It requires device manufacturers, as well as their sub-tier suppliers and contractors, to apply risk management and risk analysis from product development through product realization.

It is not uncommon for non-medical device companies to upgrade or migrate from 9001 to ISO 13485 (or to maintain both certifications) in order to introduce their existing products for use in medical applications. Device manufacturers that intend to market their products within the European Union will need to address compliance with the requirements of the applicable Medical Device Directive (MDD) and CE marking process. ISO 13485 is recognized as a critical aid in supporting compliance with the MDD.[2]

How Does ISO 13485:2003 Differ from EN ISO 13485:2012?

There are three current and common versions of ISO 13485. The primary international version is ISO 13485:2003. The variant EN ISO 13485:2012 is the latest European harmonized version of ISO 13485; it replaces the prior harmonized version, EN ISO 13485:2003, which is now considered to be obsolete. EN ISO 13485:2012 is applicable only to manufacturers placing devices on the market in Europe. Manufacturers can employ ISO 13485 to meet the quality system requirements of the European directives, including European Medical Device Directive (93/42/EEC). Confusion frequently occurs when people use the abbreviated ISO 13485 to refer to both ISO 13485:2003 and EN ISO 13485: 2012. This leads some to assume that there is a 2012 version of the primary (2003) standard, which there isn't. The third version is CAN/CSA-ISO 13485:03. Conformance to this standard is necessary in order to secure a Canadian Medical Device License for a Canadian class II, III or IV medical device. Health Canada considers this variant to be the equivalent to ISO 133485:2003.

How is the Standard Organized?

ISO 13485 comprises eight sections, which are preceded by an introduction. Sections one through three describe the purpose for and use of the standard. Sections four through eight contain the "meat" of the standard, i.e., the requirements necessary for compliance, so they will be examine individually.

- **Section Four (Systemic Requirements):** This section defines the general requirements for compliance. It explains how to implement and maintain a QMS for devices; prepare a quality manual, quality policy, and quality objectives; control QMS documents; and maintain document integrity.

- **Section Five (Management Requirements):** This section defines management's role in the establishment and maintenance of an ISO 13485 QMS. It requires upper management to actively participate in quality planning, and to ensure that the quality policy is understood throughout the organization. Specific requirements for carrying out periodic management reviews of the QMS, including how often reviews should take place; what to cover; and expected outputs, are also covered in section five.

- **Section Six (Resource Requirements):** This section defines the requirements for the provision of resources, including physical resources (e.g., the need for adequate space, tools and equipment); environmental resources (e.g., the environment must suit the type of device being made); and human resources (e.g., how to train and maintain competent personnel). Key topics covered in section six include the importance of defining employee job requirements and how to keep good training records.

- **Section Seven (Product Realization Requirements):** This extensive section covers everything that is required in order to produce a product, from customer requirements to creating (designing and manufacturing), installing, and supporting a medical device. Requirements are given for how to correctly perform the most basic tasks (e.g., processing catalog orders), as well as the most complex tasks (e.g., designing from a design concept). Validation; equipment maintenance; and risk management, including risk assessment, risk analysis and risk reduction), are also covered in section seven.

- **Section Eight (Remedial Requirements):** This final section defines the remedial processes necessary in order to maintain the effectiveness of the QMS. Key topics covered in section eight include handling adverse events and customer complaints; conducting internal audits; monitoring and measuring processes and product, including nonconforming product; analyzing data; and taking corrective and preventive actions.

ISO/TR 14969:2004 is a guidance document for application of ISO 13485. Additional guidance for implementing a medical device QMS can be obtained from the Global Harmonization Taskforce and the FDA guidance documents and compliance manual.

Is ISO 13485 Required?

ISO 13485 is required in Canada (CAN/CSA-ISO 13485:03). Japanese Ministry of Health, Labour and Welfare (MHLW) Ordinance #169 is based on ISO 13485: 2003 and is required in Japan. Although EN ISO 13485 is considered to be the de facto standard for the device industry in Europe, it is not technically a requirement. It is, however, the expectation for two reasons: certification to EN ISO 13485 presumes compliance with applicable European Directives (making it easier to obtain CE Marking, which is mandatory if you want to place a device on the market in the European Union) and it's considered good practice. In the United States, the FDA Quality System Regulation (QS Reg.), also known as cGMP, is required. Of course, if a U.S.-based company wishes to market its medical device products internationally, it must comply with both cGMP and ISO 13485.

Even in countries where adherence to the standard isn't required by law, ISO 13485 is becoming increasingly required by investors, partners and customers. A 2011 Covidien-commissioned survey of 900 device manufacturers showed that 37% of respondents had become 13485 certified to meet regulatory requirements, 31% had become compliant to support regulatory approval of products or services, and 28% had become compliant to meet customer requirements.[3] Third-party certification to a particular standard or regulation assures both potential and existing consumers, as well as suppliers and foreign trade officials, that your business operations are safe and efficient. This assurance can lead to tremendous marketing and business advantages.

Why is ISO 13485 Important?

There are many reasons why ISO 13485 certification might be important to a medical device company, including:

- **Increases customer confidence:** Certification establishes a company's commitment to quality, which often leads to increased customer confidence;

- **Enhances marketing and promotional opportunities:** Once a company has been deemed compliant by a certified ISO13485 registrar, it will receive a certificate. The company's marketing team will be able to display this

certificate on all corporate marketing materials to enhance its credibility in the eyes of customers, employees and other stakeholders;

- **Promotes better communication/fewer deviations:** ISO 13485 promotes harmonization of regulatory requirements on an international scale. Harmonization allows device manufacturers and other quality experts to communicate using a familiar/standardized vocabulary. This reduces communication gaps and misunderstandings that often result in deviations, nonconformances and other quality events that can cause patient harm, regulatory sanctions and significant revenue loss;

- **Improves performance and supplier relationships:** Using a uniform, widely-accepted system of process control leads to improved products and processes. This, in turn, often leads to increased customer satisfaction and better relationships with suppliers and partners;

- **Enhances brand equity:** Improved products and processes help device manufacturers sustain their delivery of high-quality products, and minimize or avoid embarrassing product recalls and costly regulatory sanctions. Ultimately, this leads to increased brand equity, which is an important competitive advantage;

- **Increases Speed to Market:** ISO 13485 certification allows an organization to meet the quality system requirements of the European Medical Device Directive (93/42/EEC), In Vitro Medical Device Directive (98/79/EEC) and Active Implantable Medication Device Directive (90/385/EEC) with less difficulty, which expedites market entry.

What are the Financial Benefits of ISO 13485?

Many device companies fail to realize how much money they could save (or even generate) by developing and implementing a quality management system that adheres to ISO 13485. Although the standard is not designed to make every medical device company equal in talent or ability, it is designed to help management understand how company processes correspond to ISO 13485, and why those processes work in the way that they do. In other words, the standard is designed to make the quality system transparent.

Unclear or vague documentation is often what keeps company processes and ISO 13485 compliance at odds. Once documentation presents a clear and deep understanding of how processes and standards fit together, and why they are designed as they are, it becomes easier to spot errors, avoid costly regulatory sanctions and provide effective employee training.

Clear training and understandable SOPs enable employees to understand their assigned tasks, as well as any deviations or nonconformance events they are responsible for reporting. The end result: confident employees who are more satisfied with the company, and their role within it. When employees are satisfied and productive, deviations "bubble up" through the system faster, and a positive financial impact is all but guaranteed.

According to *Quality Digest* magazine, there is more than one way to save money by adhering to ISO 13485 standards. "Having a quality management system [based on ISO 13485 standards] at an early stage provides another advantage to these companies [medical device companies]: quicker market access. Many regulatory organizations were involved in the development of this standard. Therefore, requirements in regulatory laws such as the 93/42/EEC MDD share numerous similarities with ISO 13485. Hence, after a simple update of their systems, these companies can quickly and cost-effectively seek regulatory approvals from a variety of countries."

The same article states "For medical device manufacturers, it is mission-critical to receive such certification [ISO 13485 certification] quickly. They invest in both research and development, and in the product's sales and marketing plans. Particularly in the medical device industry, the longer a product languishes in the review process, the less it returns to the manufacturer's bottom line."[3]

Medical device companies can also save a significant amount of money by automating their quality processes, a concept which will be expanded on in upcoming sections.

How Do I Prepare for ISO 13485 Certification?

Preparing for a third-party accreditation audit is a long and tedious process. Many device manufactures, particularly smaller firms, simply do not have the time, resources or expertise to assess their entire quality management system to identify and correct all of the potential barriers to certification success. If time is of the essence, or a dedicated internal resource is not

available, the company may decide to enlist the services of an experienced ISO consultant or quality management certification expert to liaise with the registration body, also referred to as the registrar.

The certification process is typically divided into five phases.[4] If the company is using the services of an ISO consultant, the consultant will often handle most—if not all—of the phases on behalf of the company. This can save the company a great deal of time and accelerate the process significantly.

Phase One: Inquiry—ISO itself does not perform certification audits or issue certificates. These services are performed by external certification bodies. Choosing a certification body is the first step of the inquiry phase. ISO's website provides some tips for selecting a certification body. For example, ISO recommends evaluating several registrars before making a final selection. It's important that the registrar you select is competent. In 2013, the European Commission published a report which found that two out of 11 notified bodies were performing so inadequately, they were ordered to stop issuing CE certificates.[5]

The evaluation process typically commences with a fact-finding meeting between the registrar and the company seeking certification. During this meeting, the registrar will attempt to gather background information about the company and its certification needs. The company will want to inquire about the registrar's working philosophy, as well as what to expect during the certification process.

Phase Two: Application—If the fact-finding meeting goes well, the company will be asked to fill out a certification application form, which can be obtained online. The registrar will review the completed application form, as well as the information gathered during the inquiry phase, and provide the company with a quote. Obviously, if the company has chosen to follow ISO's advice, it will be requesting and receiving multiple quotes, from multiple registration bodies. Once a registrar has been selected, the company is ready to advance to phase three.

Phase Three: Documentation Review—At this point in the process, the registrar will begin to assess how the company's documented quality processes compare or comply with the standard. During phase three, the company may opt to conduct a trial audit (often referred to as a pre-assessment) to get a sense of the registrar's auditing style and to see what quality areas, if any, are deficient. Although a pre-assessment is not required, it is highly recommended.

Phase Four: Final Certification Audit—For certification audits, a Stage 1 and a Stage 2 must be conducted prior to the final certification audit. The combined duration of the audits must comply with the IAF MD9 guidance document. Section 0.2 of ISO 13485 requires auditors to use a "process approach" auditing style, as opposed to a checklist approach. The process approach utilizes the plan-do-check-act (PDCA) cycle.

Phase Five: Ongoing Surveillance—Annual or semi-annual surveillance audits should be scheduled with the registrar in order to monitor progress and correction. These audits should be scheduled well in advance of the company's anniversary date. A complete assessment restarts every three years.

(Editor's note: MasterControl's Quality Compliance Consulting division offers ISO 13485 application/certification services. If you would like to learn more about QCC, visit http://www.mastercontrol.com/home_page_ads/need-consulting.html?lne=hlnk_needconsult. To learn more about automating your paper-based quality management processes with MasterControl software, and how it can facilitate the certification process, continue reading.)

Is It True That 50 Percent of Companies Fail to Obtain Recertification?

According to an article published in *Quality Digest*, most small- and medium-sized companies continue to prepare for or maintain ISO registration through manual processes. Imagine the amount of time it takes to key in or type the required quality documents, physically draw process diagrams, create reports and validate data in preparation for a registration audit. Now imagine how many days it takes for internal and external auditors to locate paperwork and manually compare the data to information provided in the application. Time isn't the only disadvantage of manual preparation; expense is also a concern. The article estimates that registrations in manual environments still cost more than $100,000, and take an average of one year of preparation. Moreover, evidence suggests that up to 50 percent of these registrations fail at the time of recertification due to a company's inability to maintain and scale manual processes.[6]

Automating quality management processes with sophisticated software tools can help manufactures not only obtain certification faster, but also maintain that certification long term. The following section explains how the MasterControl software suite facilitates ISO 13485 compliance.

MasterControl Automates Your Processes for ISO 13485 Compliance

ISO 13485 Requirements	MasterControl Features To Ensure Compliance with ISO 13485
(ISO 13485—Sections 4.1.3 and 4.2.1.2) Requires establishment of a quality management system for medical devices. A manufacturer must have quality procedures that are documented, controlled, and effectively implemented and maintained.	MasterControl helps medical device companies comply with ISO 13485 by automating routing, escalation, approval, and delivery of standard operating procedures (SOPs), policies, and other documentation. The software provides automatic revision control to ensure that only the current version of an SOP is available. When a user makes a change to the document or record, the user must enter a reason for the change. The system tracks these changes and makes them available through reports.
(ISO 13485—Section 6.2.2) A manufacturer must ensure that its personnel have the right experience, education, training, and skills. Acceptable levels of competence must be defined. Training needs must be established and assessed. A record of competence must be maintained.	MasterControl helps medical device companies comply with ISO 13485 by automating the assignment and monitoring of training tasks and grading of online exams. The software allows sequencing of training courses so after a prerequisite is completed the next course is automatically launched. It also provides a group sign-off feature for verifying training of large groups of employees.
(ISO 13485—Sections 8.2.3, 8.2.4, 8.3.2 and 8.3.3) A manufacturer must plan how remedial processes will be used to assure conformity. It must use remedial processes to demonstrate conformance. It must establish a nonconforming products procedure; nonconformances must be corrected and documented.	MasterControl helps medical device manufacturers comply with ISO 13485 by integrating the corrective and preventive action process with other quality processes. A CAPA form can be launched directly from another form (e.g., a nonconformance report). The software automatically enters relevant data into a CAPA form, reducing data entry and eliminating errors that result from the manual transfer of information. It also provides customizable reporting capabilities to help managers monitor the entire quality management life cycle.
ISO 13485—Section 4.1.2 – General Requirements A risk-based approach is needed when developing processes. Anything that effects the quality system must be viewed from a risk perspective.	MasterControl helps medical device companies comply with ISO 13485 by allowing users to configure multiple risk types for evaluating different categories of operational risk. Risk assessments can be launched from anywhere within the MasterControl system to analyze hazards associated with any process or activity. MasterControl's best practice process also include risk mitigation and risk assessment. Standardizing risk analysis methodologies and assessment results in a single location saves time, money and valuable resources.
(ISO 13485—Section 5.6.1) Requires management reviews, including examination of product conformity data.	MasterControl is a robust solution designed to help medical device manufacturers comply with ISO 13485 by automating, managing, and streamlining the process for identifying, evaluating, reviewing, and handling of nonconforming materials, components, parts and finished products. The solution's best practice form and five-step process connect all responsible personnel for effective and timely disposition of a nonconformance. In addition, the solution's scheduled reports enable management to stay on top of product conformity data by simply reviewing their email.

(ISO 13485 -- Section 7.3.1) Design and development documentation must be established. Communication and all forms of interfacing must be managed between all groups involved with the design and development processes. Planning output must also be established.	MasterControl allows medical device manufacturers to comply with ISO 13485 by enabling users to control design documentation, technical dossiers, BOM iterations and all related supplier documentation. The Project Management module also allows MasterControl users to manage all stages of design and development.

Conclusion

In today's global medical device industry, it's no longer enough to merely comply with FDA requirements. Medical device manufacturers must address the demands of regulators from countries around the world. Achieving ISO 13485 certification is a worthy endeavor since maintaining ISO standards promotes customer, investor, and employee confidence, and builds a system that is ideal for automation and increased productivity.

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